Clinical Trials Application

Please complete this application in its entirety, as the responses given are material to the provision of terms. There is space for more details in the Additional Information Section at the end of the application. Coverage may be provided on a claims-made basis.

Named Insured: _____

Street Address: _____

City: _____ Province: _____ Postal Code: _____

Contact: _____ Email: _____ Phone: _____

Section 1: Clinical Trials Details

1. Please complete this schedule of the current human clinical trials you are involved with:

Product/Protocol Name and Number	Phase	No. of Subjects		Country	Indication/ Disease Tested	Status	Revenue (If Any)
		Current	Total				

2. Are all trials conducted in accordance and registered with appropriate local government authorities? Yes O No O
3. Are all trials conducted in accordance with Ethics Committee/Research Ethics Board approval? Yes O No O
4. Are all trials conducted in accordance with I.C.H. guidelines? Yes O No O
5. Do you recruit your own subjects? Yes O No O
6. Does the clinical trial include clear informed consent for all potential participants? Yes O No O
7. Do you give medical advice or operate an inpatient facility as part of the clinical trial? Yes O No O
8. Have any Adverse Event Reports been filed on any of your products in the past 5 years? Yes O No O
9. If Yes to 8., was your product associated with death, hospitalisation, or permanent injury? Yes O No O
10. Please provide the number of Expanded Access/Compassionate Use participants: _____
11. Have any Clinical Investigators been cited for regulatory violations in connection with you? Yes O No O
12. Do your clinical trials involve any of the following: minors, infants, women that are known to be pregnant, birth control, genetic engineering, gene therapy, withdrawn pharmaceuticals, opioids, cannabis, an invasive practice or ethical implications? Yes O No O
13. Do you assume liability under contract for the product? Yes O No O
14. Does the contract have hold harmless agreements in place in the favour of your organization? Yes O No O
15. Did a member of staff or physician practicing at your facility write the clinical trial protocols? Yes O No O
16. Is the presiding physician a member of the CMPA? Yes O No O

Section 2: Claims History

1. Have you ever had a claim against your organisation's insurance policies? If Yes, please provide details including date of loss, amount paid or held in reserve, and description of allegation.* Yes O No O
2. Are you aware of any incidents or circumstances that could potentially give rise to a claim? If Yes, please provide details.* Yes O No O

*Please provide further details in the space provided under the Additional Information Section.

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Section 3: Requested Insurance Coverage

1. Please indicate the coverage limit, aggregate, retroactive date and deductible you are requesting:

Coverage	Limit	Aggregate	Deductible	Retroactive Date
Clinical Trials				

Privacy Policy

By signing this form, you are consenting to the collection, use, disclosure, and retention of your personal information for the purposes of underwriting and rating, policy issuance, processing and remitting premium, reporting claims, complying with applicable laws and governing bodies, reporting and monitoring results and fraud and criminal prevention. Please see www.signalunderwriting.com/privacy-statement for our External Privacy Policy.

Declarations

I/We, the undersigned, do declare and warrant that all statements and responses provided in this application and the attached addenda are to the best of my/our knowledge are true. Further, I/we warrant that no information has been withheld, suppressed or misstated any material facts that the underwriters may come to rely upon. I/We will notify the underwriters as soon as practicable if anything material is to change. I/We hereby agree and accept that this Declaration shall be the basis of such contract and will form part of the policy. Signing this application does not bind the underwriters or insurers to complete the insurance, nor does it bind me/us to purchase the quoted coverage.

For British Columbia residents: SIGNAL Underwriting Inc. operates as SIGNAL Underwriting Services in British Columbia.

For Quebec and New Brunswick residents: Signing this Declaration confirms your request that all documentation and correspondence pertaining to the insurance coverage be in the English language.

Name (please print)	Title	Date

Signature

Additonal Information Section

Please use this space to provide any additional information from the questions above, from the addenda or anything you feel is material to your operations:

*Please provide further details in the space provided under the Additional Information Section.

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